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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/098,644	03/15/2002	Susan A. Gregory	C2916/4 (PHA 4151.7)	7986

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EXAMINER

SEAMAN, D MARGARET M

ART UNIT.

PAPER NUMBER

1625

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/098,644

Applicant(s)

GREGORY ET AL.

Examiner

D. Margaret Seaman

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

This application was field 15 March 2002 and is a DIV of 09/430072 (filed 10-18-1999, now US Patent #5,376,528) which is a CON of 09/189,463 (filed 11-10-1998, ABN) which is a Con of 08/600,622 (filed 2-13-1996, ABN). Claims 9-20 are before the Examiner.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claims 18-20 are ambiguous due to the claims being unclear as to what is being claimed. The claims have either common names (cyclosporin) or trademarks within the claims. With cyclosporin and Cyclosporin A, there is a question as to what the difference is between the two compounds. Please note RN 79217-60-0 and RN 59865-13-3. Both of these registry compounds are known as cyclosporin. One is known as both cyclosporin and cyclosporin A. Which is being claimed? Clarification is required.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 9-20 remain rejected under 35 U.S.C. 102(b/e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Isakson (US Patent #6,136,839), Gregory (US Patent #6,407,140), WO 96/41626, and Engelhardt (CA 125:292089) and now further in

view of Talley (US Patent #5,859,257), Hagmann (US Patent #4,919,776), Isakson (US Patent #5,990,148), Mills (US Patent #6,013,644) and Finke (US Patent #6,500,844).

Isakson discloses combination of cyclooxygenase-2 (COX-2) inhibitors and 5-lipoxygenase (5-LO) inhibitors with other compounds that are anti-inflammatory compounds.

Gregory discloses combinations of cyclooxygenase-2 inhibitors, 5-lipoxygenase inhibitors with other active ingredients.

WO discloses combinations of cyclooxygenase-2 inhibitors and 5-lipoxygenase inhibitors that work as immunosuppressants for organ transplants.

Engelhard discloses a combination therapy of several active ingredients including COX-2 inhibitors, leukocyte inhibitors and 5-lipoxygenase inhibitors. Specifically, meloxicam is disclosed as part of the combination therapy. Meloxicam is a COX-2 inhibitor.


Further, to show that such combination therapies are common and well known in the art, are the following references: Talley (US Patent #5,859,257) discloses (columns 1-4) a combination of COX-2 inhibitors with 5-LO inhibitors. Hagmann (US Patent #5,919,776) discloses on columns 12-16 the combination of modulators of chemokine receptor activity with 5-LO, COX-2 and other active agents. Isakson (US Patent #5,990,148) discloses on column 1 the combination of COX-2 with 5-LO with other active ingredients. Column 2 discloses the combination with cytotoxic agents. Mills (US Patent #6,013,644) discloses on columns 21-27 the combination of 5-LO, COX-2 and anti-inflammatory agents. Finke (US Patent #6,500,844) discloses on columns 28-34 the combination of 5-LO, COX-2 and other active ingredients such as anti-inflammatory agents.

The above all show that the combination of a COX-2 inhibitor, 5-LO inhibitor and other active ingredients is well known in the art.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 703-308-4528. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


D. Margaret Seaman
Primary Examiner
Art Unit 1625

dms
February 6, 2003